

# The Vermont Statutes Online

## Title 26: Professions and Occupations

### *Chapter 67: HEARING AID DISPENSERS*

#### *Sub-Chapter 1: General Provisions*

#### **§ 3281. Definitions**

As used in this chapter:

(1) "Audiologist" means any person who has at least an M.A. or M.S. degree in audiology, at least 300 hours of supervised practical training, and is eligible for the American Speech-Language-Hearing Association Certificate of Clinical Competence in audiology, and provides services to the public under any title incorporating the terms audiology, audiologist, audiological, hearing clinic, hearing clinician, hearing or aural rehabilitation, or hearing specialist.

(2) "Disciplinary action" includes any action taken by an administrative law officer established by 3 V.S.A. § 129(j) against a licensed hearing aid dispenser or an applicant premised on a finding that the licensee or applicant has engaged in unprofessional conduct. "Disciplinary action" includes all appropriate remedies, including obtaining injunctions, refusing to grant or renew a license, suspending or revoking a license or issuing warnings.

(3) "Dispensing hearing aids" means conducting and interpreting hearing tests for the purpose of selecting suitable hearing aids, making earmolds or impressions, and providing instruction, and includes all acts pertaining to selling, renting, leasing, pricing, delivering, and giving warranties for hearing aids.

(4) "Hearing aid" means an amplifying device to be worn by a hearing-impaired person to improve hearing, including any accessories specifically used in connection with such a device, but excluding theater or auditorium wide-area listening devices, telephone amplifiers, or other devices designed to replace a hearing aid for restricted situations.

(5) "Hearing aid dispenser" includes any person who dispenses hearing aids in or into Vermont.

(6) "Director" means the director of the office of professional regulation. (Added 1989, No. 60, § 1; amended 1989, No. 250 (Adj. Sess.), § 4(b), (d); 1997, No. 40, § 49(a).)

#### **§ 3282. Records and equipment**

(a) A licensee shall maintain records relating to the sale of his or her goods and services and,

upon request, shall make such records available to the director for review. A licensee shall maintain records required to be kept under this section for a period of at least seven years from the date of the sale.

(b) A licensee shall make the testing equipment available for periodic inspection by the director or the director's designee, and shall have all testing equipment calibrated annually by the manufacturer or a qualified testing service in accordance with American National Standards Institute specifications.

(c) The director shall adopt rules implementing the provisions of this section. (Added 1989, No. 60, § 1; amended 1989, No. 250 (Adj. Sess.), § 4(d).)

### **§ 3283. Prices to be disclosed**

A licensee shall disclose in a clear and conspicuous manner the range of retail prices charged for hearing aids and accessories. The disclosure schedule shall be posted in each retail establishment in which the licensee works, and a written copy given to each customer prior to any sale. Disclosures shall be in the manner set forth by the secretary by rule. (Added 1989, No. 60, § 1.)

### **§ 3283a. Expired.**

### **§ 3284. Terms of sale; 45-day trial period**

(a) All sales contracts for hearing aids sold to persons in this state shall contain a clause which requires the hearing aid dispenser to refund the full product price of the hearing aid, except for the cost of earmolds and service, up to 45 days from the date of delivery of any new or substantially refabricated aid if, in the opinion of the consumer, the aid is not satisfactory. If the returned hearing aid is damaged while in the possession of the consumer, the amount refunded shall be reduced by the reasonable amount of the damage. The hearing aid may not be sold thereafter as new. For purposes of this subsection, "cost of service" means the actual cost of the service provided to fit the hearing aid but shall not exceed five percent of the sale price or \$50.00, whichever is greater.

(b) The complete terms of the sale, including the terms of the 45-day trial period, the individual prices for goods and services sold and such other information as the director may require shall be disclosed in writing to the consumer before the sale is completed.

(c) If a hearing aid is in the possession of the hearing aid dispenser, manufacturer, repairperson, or their agents during the trial period, the period of time the aid is in such possession shall not be included in the calculation of the 45-day trial period. (Added 1989, No. 60, § 1; amended 1989, No. 250 (Adj. Sess.), § 4(d).)

## ***Sub-Chapter 2: Administration***

### **§ 3287. Advisor appointees**

(a) The secretary shall appoint three licensed hearing aid dispensers and one member of the public to serve as advisors in matters related to hearing aid dispensers. Of the licensed hearing aid dispensers, one member shall be an otolaryngologist; one shall be an audiologist; and one shall be a hearing aid dispenser who is neither an otolaryngologist nor an audiologist. The public member shall be an individual with significant hearing impairment who uses a hearing aid regularly. The members shall be appointed as set forth in 3 V.S.A. § 129b and shall serve at the pleasure of the secretary.

(b) The director shall seek the advice of the advisors appointed under this section in carrying out the provisions of this chapter. Such members shall be entitled to compensation and necessary expenses in the amount provided in 32 V.S.A. § 1010 for attendance at any meeting called by the director for this purpose. (Added 1989, No. 60, § 1; amended 1989, No. 250 (Adj. Sess.), § 83; 2007, No. 29, § 46; 2011, No. 66, § 10a, eff. June 1, 2011.)

### **§ 3288. Director of the office of professional regulation; duties**

The director shall:

- (1) provide information to applicants for licensure as a hearing aid dispenser;
- (2) administer fees collected under this chapter;
- (3) explain appeal procedures to licensees and applicants and complaint procedures to the public;
- (4) receive applications for licensure, grant licensure under this chapter and renew licenses, and deny, revoke, suspend, reinstate, or condition licenses as directed by an administrative law officer;
- (5) refer all complaints and disciplinary matters to an administrative law officer established under 3 V.S.A. § 129(j);
- (6) seek the advice of the hearing aid dispensers who are advisor appointees before proposing to adopt or amend any rules under this chapter. (Added 1989, No. 60, § 1; amended 1989, No. 250 (Adj. Sess.), §§ 4(b), (d), 84; 1997, No. 40, § 49(a).)

### ***Sub-Chapter 3: Licenses And Examinations***

#### **§ 3291. License required**

(a) Unless a person is licensed in accordance with the provisions of this chapter, he or she shall not:

- (1) dispense or attempt to dispense hearing aids or hold himself or herself out as being able to dispense hearing aids; or
- (2) use in connection with his or her name any letters, words, or insignia indicating or

implying that he or she is a hearing aid dispenser.

(b) A person who violates a provision of this chapter or who obtains a license by fraud or misrepresentation shall be subject to the penalties provided in 3 V.S.A. § 127(c).

(c) Audiologists licensed pursuant to chapter 87 of this title may dispense hearing aids consistent with the requirements of that chapter. Licensed audiologists are not required to obtain a separate license to dispense hearing aids. (Added 1989, No. 60, § 1; amended 2001, No. 151 (Adj. Sess.), § 47, eff. July 1, 2003; 2007, No. 29, § 47.)

### **§ 3292. Construction**

(a) Nothing in this chapter shall be construed to prohibit a person from manufacturing hearing aids or making mechanical repairs to hearing aids or from issuing warranties in connection with such manufacturing or repairs.

(b) The licensure requirements of this chapter shall not be construed to apply to any person engaged in hearing aid dispensing as part of the academic curriculum of an accredited institution of higher education, provided that said person is directly supervised by a licensed hearing aid dispenser.

(c) Nothing in this chapter shall be construed to prohibit licensed practitioners from acting within the scope of practice for their licensed field. However, such practitioners shall comply with sections 3282, 3283, and 3284 of this title. (Added 1989, No. 60, § 1; amended 1991, No. 167 (Adj. Sess.), § 53.)

### **§ 3293. Eligibility**

To be eligible for licensure under this chapter, an applicant shall:

(1) have attained the age of majority; and

(2) pass a written examination administered by the secretary under section 3295 of this title. (Added 1989, No. 60, § 1.)

### **§ 3294. Application**

Applications for licensure as a hearing aid dispenser shall be made on a form furnished by the director and shall be accompanied by the application and examination fees and evidence of eligibility as requested by the director. (Added 1989, No. 60, § 1; amended 1989, No. 250 (Adj. Sess.), § 4(d).)

### **§ 3295. Examination**

(a) If any applications are pending, the director shall conduct examinations under this chapter at least twice each year. Examinations shall be administered in the manner and places designated by the director.

(b) The examination shall cover the following: the basic physics of sound, anatomy, and physiology of the ear, structure and function of hearing aids, pure tone audiometry, voice and recorded speech audiometry, interpretation of audiograms as related to hearing aid usage, selection and adaptation of hearing aids, counseling the hearing impaired, identifying situations in which referrals to a physician are appropriate, knowledge of medical and rehabilitation facilities for the hearing impaired in this state, and state and federal laws relating to dispensing hearing aids and other areas of knowledge determined by the director to be necessary.

(c) If the applicant passes the examination and meets the other requirements set forth in this chapter, the applicant shall receive a license upon payment of the license fee.

(d) If an applicant fails the examination, the applicant may retake the examination on one or more occasions upon payment of the examination fee.

(e) The director shall establish by rule fixed criteria for passing the examination that shall apply to all persons taking the examination.

(f) The director may waive the examination requirement if the applicant is a hearing aid dispenser regulated under the laws of another state who is in good standing to dispense hearing aids in that state and, in the opinion of the director, the standards and qualifications required for regulation of hearing aid dispensers in that state are currently at least equal to those required by this chapter.

(g) Licensing standards and procedures shall be fair and reasonable and shall be designed and implemented to measure and reasonably ensure that all applicants are granted licensure if they demonstrate that they possess the minimal occupational qualifications which are consistent with public health, safety, and welfare. They shall not be designed or implemented for the purpose of limiting the number or types of licensees. (Added 1989, No. 60, § 1; amended 1989, No. 250 (Adj. Sess.), § 4(d).)

#### **§ 3295a. Temporary licensure without examination**

(a) A temporary license may be issued to a person who applies for the first time to practice as a hearing aid dispenser, under section 3293 of this title, is employed by a licensed hearing aid dispenser and satisfies the provisions of subdivision (1) of that section.

(b) A temporary license allows a person to practice as a hearing aid dispenser while directly supervised by a hearing aid dispenser licensed under section 3295 of this title until he or she takes the next examination provided by the director and a determination is made of his or her qualifications to practice in this state. The supervising hearing aid dispenser shall personally observe the temporary licensee while conducting and interpreting hearing tests and making earmolds or impressions, for a period of two months following issuance of a license under this section or until the license expires, whichever occurs first.

(c) Temporary licenses shall be issued on payment of the specified fee and shall remain in force no longer than 60 days following examination and shall not be extended except for good and exceptional cause shown by the applicant. Not more than one temporary license may be issued to the same person. No extension shall be granted to an applicant who fails the examination. (Added

1991, No. 167 (Adj. Sess.), § 54.)

### **§ 3296. Renewals**

- (a) Licenses shall be renewed every two years upon payment of the renewal fee.
- (b) Biennially, the director shall forward a renewal form to each licensee. Upon receipt of the completed form and the renewal fee, the director shall issue a new license.
- (c) A license which has lapsed for a period of three years or less may be renewed upon application and payment of the renewal fee and the reinstatement fee. The director may make such rules as may be reasonably necessary for the protection of the public to assure the director that an applicant for reinstatement under this subsection is professionally qualified.
- (d) As a condition of renewal, the director may require that licensees establish that they have satisfied continuing education requirements established by the director, by rule. (Added 1989, No. 60, § 1; amended 1989, No. 250 (Adj. Sess.), § 4(d).)

**§ 3297. Repealed. 1997, No. 59, § 65(5), eff. June 30, 1997.**

### **§ 3298. Maintenance of business address; display of license**

A licensee shall maintain a Vermont business address, office, and telephone number at which the licensee can normally be reached and shall conspicuously display a copy of the license at each place of business the licensee maintains for dispensing hearing aids. (Added 1989, No. 60, § 1.)

## ***Sub-Chapter 4: Unprofessional Conduct And Discipline***

### **§ 3301. Unprofessional conduct**

- (a) A licensee shall not engage in unprofessional conduct. When such conduct is committed by an applicant it shall be grounds for denial of a license.
- (b) Unprofessional conduct means the following conduct and conduct set forth in 3 V.S.A. § 129a:
  - (1) aiding or abetting a person, directly or indirectly, to commit unauthorized practice;
  - (2) giving, offering to give, or causing to be given, directly or indirectly, money or anything of value to any person who advises another in a professional capacity, as an inducement for the professional to influence others to purchase goods or services from the licensee;
  - (3) making a representation which is intended or has a tendency to deceive the public, including:
    - (A) advertising a particular type of hearing aid for sale when such aid is not for sale;

(B) stating or implying that the use of a hearing aid will retard the progression of a hearing impairment; or

(C) misrepresenting the licensee or the licensee's business by using the word "audiologist" or similar terms if such designation is not accurate;

(4) engaging in any unfair or deceptive act or practice within the meaning of 9 V.S.A. § 2453 relating to consumer protection;

(5) using undue influence or coercion in connection with the dispensing of hearing aids;

(6) providing or promoting the sale of goods or services to a person who cannot reasonably be expected to benefit from such services or goods;

(7) willfully failing to honor any representation, promise, agreement, or warranty to a consumer;

(8) failing to make available, upon the request of a person using the licensee's services, copies of records or documents in the possession or under the control of the licensee, when those records or documents have been prepared in connection with the furnishing of services or goods to the requesting person;

(9) any of the following except when reasonably undertaken in an emergency situation in order to protect life or health:

(A) practicing or offering to practice beyond the scope permitted by law;

(B) accepting and performing occupational responsibilities which the licensee knows or has reason to know the licensee is not competent to perform; or

(C) performing occupational services which have not been authorized by the consumer or his or her legal representative;

(10) discouraging consumers in any way from exercising their right to a refund within a 45-day trial period, unreasonably delaying payment of such refunds as may be due, or deducting amounts from refunds beyond those allowed by law;

(11) failing to inform a consumer prior to sale that a medical evaluation of hearing loss prior to purchasing a hearing aid is in the consumer's best health interest;

(12) engaging in fraud in connection with any state or federally assisted medical assistance programs.

(c) After hearing, and upon a finding of unprofessional conduct, an administrative law officer may direct the director to take disciplinary action against a licensed hearing aid dispenser or applicant. (Added 1989, No. 60, § 1; amended 1989, No. 250 (Adj. Sess.), § 4(b), (d); 1997, No. 40, § 49(a); 1997, No. 145 (Adj. Sess.), § 54; 2011, No. 136 (Adj. Sess.), § 1b, eff. May 18, 2012.)

## HEARING AID DISPENSERS

### Rules Relating to the Profession

#### Part 1. General Information About the Licensing of Hearing Aid Dispensers

##### 1.1 The Purpose of Licensing

The Secretary of State's Office of Professional Regulation has been given certain powers by Vermont law. The purpose is to protect the public health, safety and welfare by setting standards, licensing applicants, and regulating licensed hearing aid dispensers.

##### 1.2 Business Location

The business location for licensing matters is the Office of the Secretary of State, Office of Professional Regulation, Redstone Office Building, 26 Terrace Street, Montpelier (the office). The mailing address is the Office of the Secretary of State, Pavilion Office Building, Montpelier, Vermont 05609-1106. The telephone number is (802) 828 - 2363, or toll-free in Vermont, (800) 439-8683. An interested person may get copies of these rules and more information about licensing and its requirements and procedures by writing or telephoning the office.

##### 1.3 Advisors to the Director of Professional Regulation

The Secretary of State appoints three licensed hearing aid dispensers to serve as advisors to the Director of Professional Regulation in matters related to hearing aid dispensers. One member is an otolaryngologist; one is an audiologist; and the third is a hearing aid dispenser who is neither an otolaryngologist nor an audiologist.

The appointees advise the director on such matters as selecting an examination, setting a passing score, making administrative policies and rules, and denying licenses.

##### 1.4 Laws that Govern Licensing

Licensing of hearing aid dispensers is governed by a specific statute that establishes the responsibilities for setting standards, issuing licenses, and regulating the profession. The law is Title 26, Vermont Statutes Annotated, Chapter 67. In addition, the director is obligated to comply with several other state laws, such as the subchapter on Professional Regulation (Title 3 Vermont Statutes Annotated, sections 121-131), the Administrative Procedure Act (Title 3 Vermont Statutes Annotated, sections 801 - 849); the Open Meeting Law (Title 1 Vermont Statutes Annotated, sections 311 -314), and the Access to Public Records Law (Title 1 Vermont Statutes Annotated, sections 315-320). These laws spell out the rights of applicants, licensed hearing aid dispensers, and members of the public. The complete text of any of these laws is available from town clerks or libraries, which should have a set of the Vermont Statutes Annotated.

#### Part 2. Information for Applicants

##### 2.1 Definitions

Terms defined in the Hearing Aid Dispensers Act, 26 V.S.A. § 3281, have the same meaning when used in these rules. In addition, when used in these rules;



- (1) "Cost of service" means the actual cost of the service provided to fit the hearing aid or hearing aids but must not exceed five percent of the sale price or \$50.00 per sale, whichever is greater.
- (2) "Director" means the director of the Office of Professional Regulation.
- (3) "Physician" means any medical doctor or osteopath licensed to practice allopathic medicine or osteopathic medicine.
- (4) "Special panel" means a panel appointed by the Secretary of State, including a public member and the appointed advisors or substitutes for them.

## **2.2 Qualifications for a License through Examination**

In order to obtain a license to dispense hearing aids in Vermont, the applicant must:

- (1) be at least 18 years old;
- (2) pass the examination; and
- (3) not be guilty of unprofessional conduct, as defined in 26 VSA § 3301

The passing score is set by the use of objective psychometric standards.

The examination is given at least twice a year, and the applicant who does not pass the examination may retake it one or more times. A special panel may waive the requirements of (3) if the applicant shows sufficient rehabilitation.

## **2.3 Licenses from other Jurisdictions**

The director may waive the examination requirement if the applicant is a hearing aid dispenser regulated under the laws of another state, who is in good standing to dispense hearing aids in that state and who was licensed by examination and the examination currently used is equivalent to Vermont's, including the criteria for passing.

## **2.4 Right to a Written Decision and Appeal**

If the director denies an application for a license, he or she shall give the applicant specific reasons in writing and inform the applicant of the right to appeal this decision to a special panel appointed by the secretary. After an opportunity to present the application and any additional information, the special panel shall affirm or reverse the director's preliminary decision. The applicant may appeal the special panel's decision to an appellate officer.

# **Part 3. Information for Licensed Hearing Aid Dispensers**

## **3.1 Renewal of License**

Licenses are to be renewed every two years. Biennially, the director shall forward a renewal form to each licensee. When the form is returned with the renewal fee, the office will issue a new certificate. This rule does not apply to lapsed licenses (see 3.2).

## **3.2 Reinstating a License**

A license which has lapsed for a period of three years or less may be renewed upon application and

payment of the renewal fee and the reinstatement fee. A license which has lapsed for more than three years may be reinstated after the applicant passes the examination. The applicant must complete a reinstatement application, which details his or her activities since the last renewal was filed.

### **3.3 Display of License, Business Address**

A licensee must maintain, in Vermont, a business address, an office and a telephone number, at which the licensee can normally be reached, and must conspicuously display a copy of the license at each place of business the licensee maintains for dispensing hearing aids.

### **3.4 Change of Name or Address**

A licensee is responsible for notifying the office promptly if he or she changes name, mailing address or business address. Failure to notify the office may result in not receiving the renewal application.

### **3.5 Records and Equipment**

(a) A licensee must maintain records relating to any sale of a hearing aid or related services and, upon request, must make such records available to the director or the buyer for review. A licensee must maintain the required records by a reasonably reliable method for at least seven years from the date of sale, including:

- > (1) contracts and retail installment sales agreements;
- (2) hearing test results;
- (3) waivers signed by the consumer; and
- (4) a record of payments and refunds.

(b) Testing equipment used by a licensee must be available for inspection during normal business hours, and must be calibrated annually, as provided in 26 VSA §3282. A copy of the calibration report must be kept on file and provided to the director's inspector on request.

### **3.6 Prices to be Disclosed**

(a) A licensee must disclose in a clear and conspicuous manner the range of retail prices charged for hearing aids and accessories. The disclosure schedule must include the ten brands of hearing aids most frequently sold, and show the highest and lowest prices for each brand. The most expensive and the least expensive brands sold must be included on the list. The schedule must also show the range of prices for batteries.

(b) The disclosure schedule must be posted in each retail establishment in which the licensee works, in a location which is easily accessible in the waiting area of the dispenser's office at eye level. The price disclosure shall be in not less than fourteen point boldface type and "one and a half" spacing, or the handhand letteredivalent.

This sentence is an example of fourteen point boldface type with one and a half spacing.

A typed copy, in twelve point or pica type, must be given to each customer prior to any sale.

### **3.7 Required Clauses in Contracts**

(a) At the time of each sale, immediately before completion, the dispenser shall provide to the buyer a

written statement showing the complete terms of sale, including the individual prices of the goods and services sold, the brand, model number, serial number, whether the hearing aid is new or used, the dispenser's telephone number and the date of delivery, to be filled in upon delivery. The written statement shall include or be accompanied by a disclosure in substantially the following form:

**Notice of 45 day trial period** You have 45 days from the day that you receive your hearing aid to try it out and decide whether you wish to keep it. The 45 day period does not include any days that the hearing aid is in the possession of the dispenser, manufacturer, repairer or their agents. If, in your opinion, during the 45 day trial period you feel that the hearing aid is not satisfactory for you, you have a right to return the hearing aid and receive a refund of the full product price except for the cost of ear molds and service. This refund will be at least \$\_\_\_\_\_. (Enter price minus cost of ear mold & service\*). However, if you have damaged the hearing aid, your refund will be reduced by the reasonable cost of damage.

> In order to return the hearing aid and receive a refund, contact \_\_\_\_\_ (enter name of dispenser) at \_\_\_\_\_ (enter address of dispenser) not later than 45 days after delivery of the hearing aid.

\*"Cost of service" means the actual cost of the service provided to fit the hearing aid or hearing aids but must not exceed five percent of the sale price or \$50.00 per sale, whichever is greater.

(b) At the time of delivery, the delivery date shall be entered on the sales contract.

(c) If the hearing aid is delivered at a time other than when a contract is signed, it shall be accompanied by a notice of the 45 day trial period as specified in section (a) above.

(d) At the time of sale, the dispenser shall give the buyer a written copy of any audiometric test performed.

### **3.8 Refunds**

A dispenser shall pay any refund requested during the 45 day trial period within four weeks of receiving a returned hearing aid or, if the hearing aid has not been delivered, within four weeks of the request. Failure to pay the refund within the four weeks shall be considered an unreasonable delay of a refund for purposes of 26 VSA §3301(14) (unprofessional conduct).

### **3.9 Complaints, Investigations and Unprofessional Conduct**

The Office maintains procedures for the investigation of complaints, holding hearings and taking disciplinary action. Contact the Office for copies of the procedures.

Effective date: 25 December 1991

## Regulatory Standards

The U.S. hearing aid industry adheres to comprehensive federal regulations governing both hearing aids and hearing aid sales practices. The U.S. Food and Drug Administration (FDA) enforces regulations that deal specifically with the manufacture and sale of hearing aids because these products are recognized as medical devices. The Federal Trade Commission (FTC) is responsible for monitoring the advertising and marketing practices of every business in America, including hearing aid dispensers.

The most notable federal regulation is the FDA's Hearing Aid Rule promulgated in August 1977. The rule requires that prior to the sale of a hearing aid, the practitioner advise the patient that it is in their best health interest to see a physician, preferably one specializing in diseases of the ear, before purchasing a hearing aid. The rule requires that a person obtain a medical evaluation of hearing loss within six months prior to obtaining a hearing aid or sign a waiver. The waiver provision is included to protect individual rights and freedom of choice. The FDA pointed out that medical evaluation by a physician is necessary in determining the cause of, and the pathology associated with, the patient's hearing loss.

A patient age 18 or older can sign a waiver for a medical examination, but dispensers must advise the patient that waiving the examination is not in the patient's best health interest.

The FDA regulations require that a user instruction brochure be provided prior to purchase that illustrates and describes its operation, use and care. The brochure also must list sources for repair and maintenance and include a statement that the use of a hearing aid may be only part of a rehabilitative program.

Dispensers are required to advise a prospective patient to consult promptly with a licensed physician (preferably a physician who specialized in diseases of the ear) if it is determined through inquiry, actual observation or review of any other available information that the prospective user has any of eight noted otologic conditions.

Under the Federal Trade Commission Act, the FTC can take action against a company that misleads or deceives consumers. The Magnuson-Moss Warranty Act, which the FTC enforces, provides consumers with certain protections relating to warranties. This act requires a company offering a warranty to fully disclose all its items and conditions. In addition, the FTC mandates a three-day period that offers consumers who purchase any products outside the seller's place of business the right to cancel the sale within 72 hours and obtain a full refund.

In addition to federal regulations, all states have specific laws that apply to the sale of hearing aids. All practitioners engaged in the fitting and dispensing of hearing aids must comply with all licensing requirements existing in the state of their individual practice. The state Attorney General's Office can provide consumers with particular information about state laws that apply to the sale of hearing aids and whether hearing aid dispensers must be licensed or registered by the state.



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## Buying a Hearing Aid

More than 35 million Americans suffer from some degree of hearing loss. If you're one of them, you may be shopping for an assistive device. Before you buy any product to enhance your hearing, it's important to understand the various types of hearing loss, the differences between a hearing aid and a personal sound amplification device, and what to consider when you're shopping so you get the product that's most appropriate for your particular kind of hearing loss.

What are the common types of hearing loss? Three types of hearing loss are the most common:

- **Conductive hearing loss**, which involves the outer ear, the middle ear, or both. It usually results from a blockage from earwax, fluid in the middle ear, or a punctured eardrum. Conductive hearing loss often can be corrected surgically.
- **Sensorineural — or “nerve” — hearing loss**, which involves damage to the inner ear. It can be caused by disease, illness, age, injury from exposure to noise or certain medicines, or a genetic disorder. Usually, sensorineural hearing loss can't be repaired surgically, but it can be corrected with a hearing aid.
- **Mixed hearing loss**, which is a combination of sensorineural and conductive hearing loss. Only a small portion of adult hearing problems, like ear infections and middle ear diseases, are medically or surgically treatable. If the hearing loss can't be treated medically or surgically, a hearing aid may be beneficial.

**Sound Advice:** *If you think you are losing your hearing, see your doctor. You may be referred to a health care professional who specializes in ear health and hearing loss.*

### What is a Hearing Aid?

A hearing aid is a small electronic device worn in or behind the ear. The device has three parts: a microphone, an amplifier, and a speaker. It receives sound through the microphone, which converts the sound to electrical signals and sends them to the amplifier. The amplifier increases the power of the signals and sends them to the ear through the speaker.

The device doesn't work unless you have some ability to hear. And because hearing loss affects people in different ways, you need to get the device that's appropriate for your condition. For example, if you have hearing loss in both ears, two hearing aids may

be recommended because two aids provide a more natural signal to the brain.

The price of a hearing aid can range from hundreds to thousands of dollars, depending on the style and features.

**Sound Advice:** *Price is a factor, but it's not the only one to consider when you are determining your best option for an assistive hearing device. A more expensive device isn't always better for your needs.*

## What Is a Personal Sound Amplification Product?

A personal sound amplification product (PSAP) is a device used by people with normal hearing to amplify hard-to-hear sounds. For example, if you are sitting at the back of a lecture hall, eating in a crowded restaurant, or bird-watching, a PSAP may be helpful.

**Sound Advice:** *If your hearing is impaired, don't use a PSAP as a substitute for a hearing aid. That may delay the diagnosis of a potentially treatable condition, and cause more damage to your hearing.*

## Who Can Help Me Determine the Most Appropriate Product?

Your doctor may refer you to a hearing health professional for an examination and evaluation. It may be an otolaryngologist, an audiologist, or a hearing aid dispenser. Only two types of people are authorized to measure hearing loss and fit and dispense hearing aids in the U.S.: an audiologist and a hearing aid dispenser.

- An *otolaryngologist* is a physician who specializes in diagnosing and treating diseases of the head and neck, especially those involving the ears, nose, and throat (ENT).
- An *audiologist* is a trained professional who measures hearing loss and can fit hearing aids. An audiologist has at least a master's degree and has specialized training in hearing loss; many now have an AuD (doctorate) degree, too. Some may even have a PhD.
- A *hearing aid dispenser* is someone authorized by the state to measure hearing and to fit and sell hearing aids. The credentials for becoming a hearing aid dispenser vary by state, but typically involve working as an apprentice to an already certified dispenser for some period of time and passing a test about hearing aids. A hearing aid dispenser is not an audiologist and does not have to have a college degree related to hearing loss.

Sometimes, hearing loss can be a symptom of a medical condition. A medical examination may uncover any underlying illnesses or medical problems associated with your hearing loss. In fact, a medical evaluation is so important that the U.S. Food and Drug Administration (FDA) requires hearing aid sellers to tell you about your need for a medical examination before you buy a hearing aid. If you decide to forgo an evaluation, you must sign a waiver.

**Sound Advice:** *Don't patronize a business that dismisses the need for a medical examination prior to the purchase of a hearing aid.*

## What's a Good Way to Shop for a Hearing Aid?

Once you've had a medical examination and determined that a hearing aid will help you, look for a hearing health professional who offers products from several manufacturers. You can check out sellers with your local Better Business Bureau, your state or local consumer protection agency, your state Attorney General, your state licensing or certification boards, or the American Speech-Language-Hearing Association (ASHA). These organizations may have records of complaints against licensed hearing health professionals, and can tell you how they responded to the complaints. You also may be able to enter the professional's name and the manufacturer's name into a search engine online, and find out what other people have to say.

## What About a Purchase Agreement?

Your contract should contain information about the following items:

- **Trial Period** – Most states require a 30- to 60-day trial period. Most hearing health professionals offer this even in states that don't require it. Find out what fees are refundable if you return the aid during the trial period. Make sure that's written into the purchase agreement.
- **Warranty** – Get the details. How long is the warranty? Can it be extended? Does it cover maintenance and repairs? Is it honored by the manufacturer or by the licensed hearing health care professional? In some cases, a manufacturer may not honor its warranty unless the hearing aid is purchased from an authorized seller. You also may be protected by implied warranties created by state law.
- **Loaner** – Ask if you'll get a free loaner hearing aid if your device needs servicing or repair.
- **Total Price** – Check whether the price quoted includes testing and other services, as well as the hearing aid.

While health insurance plans, including Medicare, typically pay for diagnostic hearing evaluation, many plans do not cover hearing aids. If you can't afford a hearing aid, contact the National Institute on Deafness and Other Communication Disorders (NIDCD) for information about organizations that offer financial assistance.

**Sound Advice:** *Take your time when you are shopping for a hearing aid. Resist sales pressure. It's an expensive purchase, so buy only when you're satisfied with the answers to your questions. Make sure the person you are dealing with puts any promises or guarantees about service and maintenance into the purchase agreement.*

## What are the Government's Standards for Hearing Aid Sales?

The FTC enforces regulations that prohibit the use of misleading sales and advertising

practices, including giving inaccurate information about hearing loss, hearing aid performance, refund policies, or warranty coverage.

The FDA enforces regulations that deal with the manufacture and sale of hearing aids. Before selling a hearing aid, a dispenser must:

1. get a written statement from the patient, signed by a licensed physician. The statement must say that the patient's ears have been medically evaluated, and that the patient is cleared for fitting with a hearing aid. The medical evaluation must have taken place in the preceding six months.
2. avoid encouraging the patient to waive the medical evaluation requirement. Dispensers also must advise the patient that waiving the examination is not in his best health interest.
3. advise patients who appear to have a hearing problem to consult a physician promptly.
4. provide an instruction brochure with the hearing aid that illustrates and describes its operation, use, and care. The brochure must list sources for repair and maintenance, and include a statement that the use of a hearing aid may be only part of a rehabilitative program that might also need to include auditory training and instruction in lipreading.

Many states also have laws governing hearing aid sales and implied warranties. Your state Attorney General's office can tell you what laws apply in your state.

***Sound Advice:*** *Buying a hearing aid online or through the mail is risky. In fact, some states don't allow hearing aids to be sold through the mail at all. That's because an aid needs to be custom fitted and tested to be sure it's working properly.*

## Where Can I Get More Information?

[Food and Drug Administration \(FDA\)](#)

[National Institute on Deafness and Other Communication Disorders \(NIDCD\)](#)

## What If I Want to Complain About a Device?

To report problems with medical devices, including hearing aids, contact the FDA [via the MedWatch program](#) (MedWatch Online Reporting Form 3500).

To report deceptive business practices or other types of consumer fraud, contact:

[Federal Trade Commission](#)

[Your state Attorney General](#)

[Better Business Bureau](#)



Your local consumer protection office

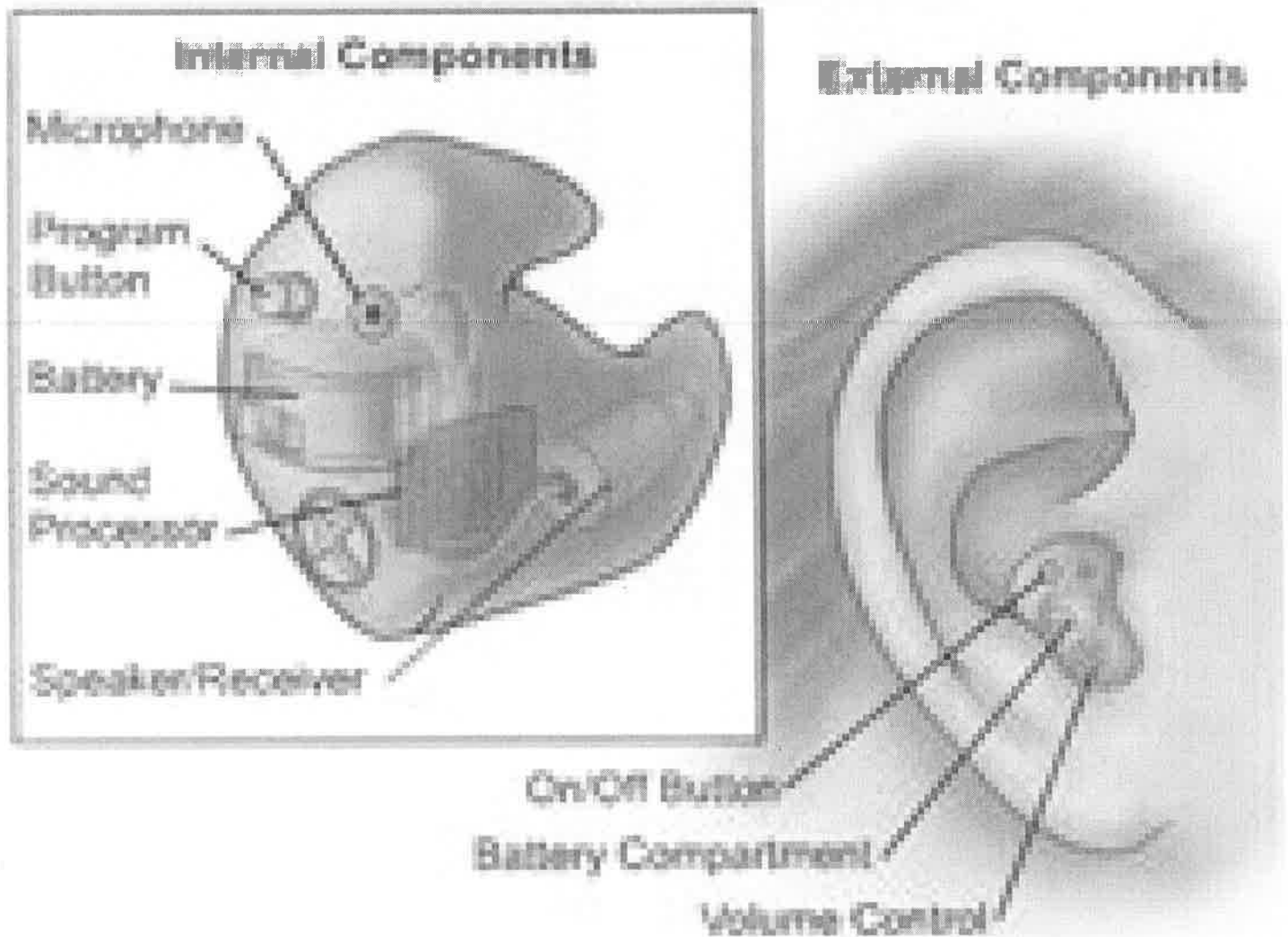
This article was previously available as *Sound Advice on Hearing Aids*.

September 2010

**U.S. Food and Drug Administration**  
Protecting and Promoting *Your* Health

# Hearing Aids

## Hearing Aid Device



### View movie

(/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/HearingAids/ucm184675.htm) about Hearing Aids

(Requires Flash Player - **Download now**

([http://www.macromedia.com/shockwave/download/download.cgi?](http://www.macromedia.com/shockwave/download/download.cgi?P1_Prod_Version=ShockwaveFlash)

**P1\_Prod\_Version=ShockwaveFlash**))

Having trouble hearing? Over 35 million children and adults in the United States have some degree of hearing loss. Hearing loss can have a negative effect on communication, relationships, school/work performance, and emotional well-being. However, hearing loss doesn't have to restrict your daily activities. Properly fitted hearing aids and aural rehabilitation techniques can help in many listening situations. Aural rehabilitation helps a person focus on adjusting to their hearing loss and the use of their hearing aids. It also explores assistive devices to help improve communication. Hearing aids for both ears are typically the norm for most hearing impaired people, but some may need only one hearing aid.

This site provides general information on hearing aids, types of hearing loss, different types and styles of hearing aids, how to get a hearing aid, benefits and safety of hearing aids, hearing aids and cell phones, other products and procedures to improve hearing, and a checklist of steps to remember and consider before purchasing a hearing aids.

This site also includes information on the difference between hearing aids and **sound amplifiers** ([//MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/HearingAids/ucm181482.htm](http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/HearingAids/ucm181482.htm)) that amplify environmental sounds for consumers with no hearing loss. FDA regulates hearing aids, which are intended to compensate for hearing loss. On the other hand, FDA does not consider sound amplifiers to be medical devices when labeled for recreational or other use by individuals with normal hearing. However, certain safety regulations related to sound output levels still apply to these products.

This site provides general information on hearing aids and is not intended to provide medical advice. If you have questions about your health, the best source of information is your hearing health care professional.

# Hearing Loss

- What are the signs and symptoms of hearing loss?
- What are the different types of hearing loss?

## What are the signs and symptoms of hearing loss?

You may have a hearing loss if:

- people say you are shouting when you talk to them
- you need the TV or radio turned up louder than other people
- you often ask people to repeat themselves because you can't hear or understand them, especially in groups or when there is background noise
- you can hear better out of one ear than the other
- you have to strain to hear
- you can't hear a dripping faucet or a high pitched note of a violin
- you think people 'mumble' when they speak

If you have any of these signs and symptoms, you should see your doctor or hearing healthcare professional to be tested for hearing loss.



Top

## What are the different types of hearing loss?

- **Sensorineural** - a hearing loss that usually develops due to damage to the small sensory cells in the inner ear, called hair cells. This damage can occur as a result of disease, illness, age, injury from exposure to noise or certain medicines, or as the result of a genetic disorder.
- **Conductive** – a hearing loss that occurs when sound waves cannot transmit through the outer or

middle ear or both. This can, for example, be caused by earwax, fluid in the middle ear space, or a punctured eardrum. Medical or surgical treatment can often restore hearing in people with a conductive hearing loss.

- **Mixed** – a combination of sensorineural and conductive hearing loss.

Only a relatively small portion of adult hearing problems, such as ear infection and middle ear diseases, are medically or surgically treatable. If the condition cannot be treated medically or surgically, hearing aids may be beneficial.



Top

# Types of Hearing Aids

- What are hearing aids?
- What are the different styles of hearing aids?
- What is the difference between analog and digital hearing aids?
- What are some features for hearing aids?

## What are hearing aids?

Hearing aids are sound-amplifying devices designed to aid people who have a hearing impairment.

Most hearing aids share several similar electronic components, including a microphone that picks up sound; amplifier circuitry that makes the sound louder; a miniature loudspeaker (receiver) that delivers the amplified sound into the ear canal; and batteries that power the electronic parts.

Hearing aids differ by:

- design
- technology used to achieve amplification (i.e., analog vs. digital)
- special features

Some hearing aids also have earmolds or earpieces to direct the flow of sound into the ear and enhance sound quality. The selection of hearing aids is based on the type and severity of hearing loss, listening needs, and lifestyle.



Top

## What are the different styles of hearing aids?

## Styles of Hearing Aids



**Behind-the-ear (BTE)**



**"Mini" BTE**



**In-the-ear (ITE)**



**In-the-canal (ITC)**



Completely-in-canal  
(CIC)

Courtesy of NIDCD/NIH

**Behind-the-ear (BTE) aids:** Most parts are contained in a small plastic case that rests behind the ear; the case is connected to an earmold or an earpiece by a piece of clear tubing. This style is often chosen for young children because it can accommodate various earmold types, which need to be replaced as the child grows. Also, the BTE aids are easy to be cleaned and handled, and are relatively sturdy.

**"Mini" BTE (or "on-the-ear") aids:** A new type of BTE aid called the mini BTE (or "on-the-ear") aid. It also fits behind/on the ear, but is smaller. A very thin, almost invisible tube is used to connect the aid to the ear canal. Mini BTEs may have a comfortable ear piece for insertion ("open fit"), but may also use a traditional earmold. Mini BTEs allow not only reduced occlusion or "plugged up" sensations in the ear canal, but also increase comfort, reduce feedback and address cosmetic concerns for many users.

**In-the-ear (ITE) aids:** All parts of the hearing aid are contained in a shell that fills in the outer part of the ear. The ITE aids are larger than the in-the-canal and completely-in-the-canal aids (see below), and for some people may be easier to handle than smaller aids.



***In-the-canal (ITC) aids and completely-in-the-canal (CIC) aids:*** These hearing aids are contained in tiny cases that fit partly or completely into the ear canal. They are the smallest hearing aids available and offer cosmetic and some listening advantages. However, their small size may make them difficult to handle and adjust for some people.



Top

## What is the difference between analog and digital hearing aids?

**Analog hearing aids** make continuous sound waves louder. These hearing aids essentially amplify all sounds (e.g., speech and noise) in the same way. Some analog hearing aids are programmable. They have a microchip which allows the aid to have settings programmed for different listening environments, such as in a quiet place, like at a library, or in a noisy place like in a restaurant, or in a large area like a soccer field. The analog programmable hearing aids can store multiple programs for the various environments.

As the listening environment changes, hearing aid settings may be changed by pushing a button on the hearing aid. Analog hearing aids are becoming less and less common.

**Digital hearing aids** have all the features of analog programmable aids, but they convert sound waves into digital signals and produce an exact duplication of sound. Computer chips in digital hearing aids analyze speech and other environmental sounds. The digital hearing aids allow for more complex processing of sound during the amplification process which may improve their performance in certain situations (for example, background noise and whistle reduction). They also have greater flexibility in hearing aid programming so that the sound they transmit can be matched to the needs for a specific pattern of hearing loss. Digital hearing aids also provide multiple program memories. Most individuals who seek hearing help are offered a choice of only digital technology these days.



Top

## What are some features for hearing aids?

Hearing aids have optional features that can be built in to assist in different communication situations. For example:

- ***Directional microphone*** may help you converse in noisy environments. Specifically, it allows sound coming from a specific direction to be amplified to a greater level compared to sound from

other directions. When the directional microphone is activated, sound coming from in front of you (as during a face-to-face conversation) is amplified to a greater level than sound from behind you.

- **T-coil (Telephone switch)** allows you to switch from the normal microphone setting to a "T-coil" setting in order to hear better on the telephone. All wired telephones produced today must be hearing aid compatible. In the "T-coil" setting, environmental sounds are eliminated, and sound is picked up from the telephone. This also turns off the microphone on your hearing aid so you can talk without your hearing aid "whistling."

The T-coil works well in theaters, auditoriums, houses of worship, and other places that have an induction loop or FM installation. The voice of the speaker, who can be some distance away, is amplified significantly more than any background noise. Some hearing aids have a combination "M" (Microphone) / "T" (Telephone) switch so that, while listening with an induction loop, you can still hear nearby conversation.

- **Direct audio input** allows you to plug in a remote microphone or an FM assistive listening system, connect directly to a TV, or connect to other devices such as your computer, a CD player, tape player, radio, etc.
- **Feedback suppression** helps suppress squeals when a hearing aid gets too close to the phone or has a loose-fitting earmold.

The more complicated features may allow the hearing aids to best meet your particular pattern of hearing loss. They may improve their performance in specific listening situations; however, these sophisticated electronics may significantly add to the cost of the hearing aid as well.



Top

# Benefits and Safety Issues

- What are the benefits of hearing aids?
  - Are there limitations with hearing aids?
  - Are there safety issues I should know about?
- 

## What are the benefits of hearing aids?

- You will be able to hear sounds that you have not heard previously.
- You will be able to hear speech over the telephone more clearly.
- You will be able to communicate more easily with family and friends.
- Your ability to communicate may improve in noisy listening situations (e.g. a restaurant or in a large group of people).



Top

## Are there limitations with hearing aids?

- Hearing aids do NOT restore normal hearing. In contrast, eyeglasses can restore 20/20 vision.
- Hearing aids amplify all sounds, including background noise that you do not wish to hear.
- Hearing aids require an adjustment period that may take several months. Follow-up visits with the licensed hearing aid dispenser are necessary to take full advantage of the hearing aids.
- When you begin to use hearing aids, many sounds, including your own voice, might seem too loud.
- You will need to learn how to adjust the settings for hearing aids with more complicated technology.
- Hearing aids can be expensive.

To overcome the potential limitations with hearing aids, inclusion of aural rehabilitation during the process of your hearing aid purchase can be helpful. Aural rehabilitation may assist in maximizing the benefits of hearing aids and developing strategies to deal with hearing aid limitations. For more information about aural rehabilitation, please see the American Speech-Language-Hearing Association's (ASHA) "[Adult Aural/Audiologic Rehabilitation](http://www.asha.org/public/hearing/treatment/adult_aur_rehab.htm) ([http://www.asha.org/public/hearing/treatment/adult\\_aur\\_rehab.htm](http://www.asha.org/public/hearing/treatment/adult_aur_rehab.htm))."  
([/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm](http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm))

▲ Top

## Are there safety issues I should know about?

Hearing aids should be properly fitted by a licensed hearing healthcare professional (such as an audiologist or a hearing aid dispenser) so that the amplification matches your hearing loss. If not fitted properly, too much amplification may cause additional hearing loss..

▲ Top

# Hearing Aids and Cell Phones

- What is that buzzing noise in my cell phone?
  - What should I look for in a cell phone?
  - What do these ratings mean?
- 

## What is that buzzing noise in my cell phone?

People who wear hearing aids or have implanted hearing devices may experience some difficulties when trying to use cell phones. That buzzing noise you hear is interference due to radiofrequency (RF) emissions from your phone. RF interference does not occur for all combinations of digital wireless telephones and hearing aids. However, when interference does occur, the buzzing sound can make understanding speech difficult, communication over cell phones annoying, and, in the worst case, render the cell phone unusable for the hearing aid user.

Fortunately, the compatibility of cell phones and hearing aids is improving. Some cell phones have lower radiofrequency emissions or use different technologies that can reduce the unwanted effects on hearing aids.



Top

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## What should I look for in a cell phone?

Rules set by the Federal Communications Commission (FCC) make it easier for you to choose a cell phone right for you. The FCC requires cell phone manufacturers to test and rate their wireless handsets' hearing aid compatibility using the American National Standards Institute (ANSI) C63.19 standard. These ratings give an indication of the likelihood that a cell phone may interfere with hearing aids; the higher the rating, the less likely the cell phone-hearing aid combination will experience undesired interference.

Labeling on the outside packaging of cell phones will tell you if they are hearing aid compatible (HAC). Hearing aid users should read and understand these ratings when choosing a cell phone. For more information, see [Hearing Aids and Cell Phones \(/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/HomeBusinessandEntertainment/CellPhones/ucm116327.htm\)](http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/HearingAids/ucm116327.htm).



Top

## What do these ratings mean?

Cell phones that are rated “good” or “excellent” for use with hearing aids set in microphone (M) mode will have a rating of M3 or M4. The higher the “M” rating, the less likely you will experience interference when the hearing aid is set in the microphone mode while using the cell phone.

Cell phones are also rated with hearing aids or cochlear implants that have a T-coil. (See Types of Hearing Aids, [What are some features for hearing aids? \(ssLINK/ucm181470.htm#4\)](http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/HearingAids/ucm181470.htm#4)) Note: Link the underline to that section) Those rated “good” or “excellent” for use with hearing aids set in T-coil mode will have a rating of T3 or T4. The higher the “T” rating, the less likely you will experience interference when the hearing aid is set in the T-coil mode while using the cell phone.

Hearing aid manufacturers use a similar rating system. The hearing aid ratings and the cell phone ratings can be combined to help identify combinations that will provide you with a positive experience. So, a hearing aid rated M2 and a wireless device rated M3 with a combined rating of 5 and would likely provide “normal” use. A ratings combination of 6 would likely provide “excellent performance”. Every individual's hearing aid technology and settings are unique; therefore, these ratings do not guarantee performance.

Because these HAC ratings do not guarantee performance, you should “try before you buy” any wireless device if possible. You should try different brands and models to see which phone works best for you. Also, be sure to closely examine the return policy for the device and the service provider's policy on early termination of contracts before signing up for service.



Top

# How to get Hearing Aids

- How do I get hearing aids?
- What if I don't want to have a medical examination?
- Where should I go to get hearing aids?
- What questions should I ask before buying hearing aids?
- How do I choose hearing aids?
- How do I know if hearing aids work for me?
- How do I care for my hearing aids?

## How do I get hearing aids?

To get hearing aids, you should first have a hearing evaluation to determine the type and amount of your hearing loss. The process begins with a medical and audiologic examination.

- **Medical examination.** The medical examination may be performed by any licensed physician including your family doctor or pediatrician, but preferably should be done by an ear, nose, and throat specialist (an otolaryngologist). You will need an examination of your ear, nose, and throat and possibly other testing to rule out any medical reason for your hearing loss, such as infection, injury or deformity, ear wax in the ear canal, and, in rare cases, tumors. You will receive documentation of your medical exam and a statement that says you are a hearing aid candidate.
- **Audiological examination.** An audiological exam, or audiogram, involves a hearing evaluation by a hearing health professional who specializes in evaluation, non-medical treatment, and rehabilitation of hearing loss (an audiologist) to identify the type and amount of your hearing loss, to determine the need for medical/surgical treatment and/or referral to a licensed physician, and to provide rehabilitation of the hearing loss.



Top

## What if I don't want to have a medical examination?

The law requires that patients intending to buy hearing aids must either have a medical exam or sign a waiver saying they do not want a medical exam to rule out a medical reason for their hearing loss before buying hearing aids. **FDA believes that it is in your best health interest to have a medical examination by a licensed physician -- preferably one that specializes in ear diseases -- before buying hearing aids.**

[Top](#)

## Where should I go to get hearing aids?

We recommend that patients with hearing loss go to a hearing healthcare professional (for example, an audiologist or a hearing aid dispenser), as appropriate, for a hearing assessment and hearing aid evaluation. We also recommend that a person with hearing loss have a medical evaluation by a licensed physician (preferably one who specializes in diseases of the ear, such as an otolaryngologist) when purchasing a hearing aid. The hearing healthcare professional will assess the person's ability to hear sounds and understand others with and without a hearing aid(s) and select and fit a hearing aid(s) to the person's individual communication needs. To find out if an audiologist or hearing aid dispenser is licensed, check with your local Better Business Bureau, consumer protection agency, State Attorney General's office, or the American Speech-Language-Hearing Association (ASHA).

[Top](#)

## What questions should I ask before buying hearing aids?

Before you buy a hearing aid, ask your hearing healthcare professional these questions:

- Which type and style of hearing aids would most meet my needs?
- What special features do my hearing aids need to have to fit my lifestyle?
- Will I need one or two hearing aids?
- What is the total cost of the hearing aids?
- Do the benefits of newer technologies outweigh the higher costs?
- Is there a trial or adjustment period for me to try out the hearing aids? (Most manufacturers allow a



trial/adjustment period during which aids can be returned for a refund.)

- What fees are nonrefundable if I return the hearing aids after the trial/adjustment period?
- How long is the warranty? Can it be extended?
- What is covered during the period of warranty? Does the warranty cover future maintenance and repairs? Will loaner aids be provided when repairs are needed?
- How should I care for my hearing aids?

[Top](#)

## How do I choose hearing aids?

It is important to select the hearing aids that are convenient and easy for you to use, and provide the best compensation for your hearing loss. You will want to wear your hearing aids regularly. Other features to consider include parts or services covered by the warranty, estimated schedule and costs for maintenance and repair, options and upgrade opportunities, and the hearing aid company's reputation for quality and customer service.

You should ask your dispenser if the hearing aids you choose provides a trial/adjustment period during which your hearing aids can be returned for a refund. Most states require a mandatory trial/adjustment period. A trial/adjustment period will allow you to test out your hearing aids to see if it works well for you.

[Top](#)

## How do I know if hearing aids work for me?

It takes time and patience to get use to hearing aids. You should wear your aids regularly to help you maximize the benefits of your hearing aids. Get familiar with your hearing aids and their features. Practice putting the hearing aids in and taking them out. Learn to adjust the volume in different listening environments. Test your aids in various listening environments and determine where you have problems hearing. Talk to your hearing healthcare professional about any problems hearing with your aids, and have changes made to your hearing aid settings if necessary. Work with your hearing healthcare professional until you are comfortable and satisfied with your hearing aids.

[Top](#)

## How do I care for my hearing aids?

Proper maintenance and care is important in extending the life of your hearing aids.

- Avoid using solvents, alcohol, or water on hearing aids because they can cause damage to the internal electronics of the hearing aid.
- Avoid exposing hearing aids to heat because this can damage them. For example, leaving them in sun or in the car, placing them in or near a microwave or conventional oven, or using a hair dryer on them.
- Clean hearing aids as instructed. Earwax and ear drainage can damage your aids.
- Avoid using hairspray and other hair care products while wearing your hearing aids.
- Turn off your hearing aids when not in use.
- Replace dead batteries immediately.
- Keep batteries and hearing aids away from children and pets.
- Visit your hearing healthcare professional on a regular basis to have your hearing aids inspected.

 [Top](#)

# Federal Regulation of Hearing Aids

By Erica Campbell

**T**here are two governing bodies that enforce federal regulations pertaining to hearing aids—the Food and Drug Administration (FDA) and the Federal Trade Commission (FTC). The FDA enforces regulations pertaining to the manufacture and sale of hearing aids, and the FTC enforces regulations that prohibit misleading sales and advertising practices (e.g., providing inaccurate information about hearing aid performance or refund policies). The most frequently referenced FDA regulations are outlined in the *Code of Federal Regulations* Title 21, Sections 801.420 and 801.421 (last revised on April 1, 2011). The FTC works to prevent fraudulent, deceptive, and unfair business practices in the marketplace, and to provide information to help consumers spot, stop, and avoid such business practices. The FTC offers specific guidance to consumers in a document titled *Sound Advice on Hearing Aids*, which is described in more detail later in this article.

## Discussion of FDA Regulatory Requirements

While it is not an audiologist's responsibility to monitor a hearing aid manufacturer's compliance with the FDA regulations, it is important for audiologists to be aware of the regulatory environment affecting manufacturers as

well as audiologists, and protections available to audiology patients. The following discussion sets forth the responsibilities of the parties under the FDA regulations.

Prior to the purchase of hearing aids, the dispenser must obtain a written statement, signed by a licensed physician, stating that the patient has been medically evaluated and cleared for fitting with a hearing aid. This evaluation must have taken place within the preceding six months. If the patient is 18 years of age or older, he or she may be provided the opportunity to waive the medical evaluation; however, the dispenser must inform him or her that the waiver is not in the user's best health interest. Additionally, the patient must not be actively encouraged to waive the medical evaluation.

If the patient decides to waive the medical evaluation, he or she must sign the following statement:

I have been advised by \_\_\_\_\_ (dispenser's name) that the Food and Drug Administration has determined that my best health interest would be served if I had a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing aid.

I do not wish a medical evaluation before purchasing a hearing aid.

The patient should be advised to consult a licensed physician (preferably an ear specialist) prior to hearing aid fitting if any of the following conditions are present:

- Visible congenital or traumatic deformity of the ear.
- History of active drainage from the ear within the previous 90 days.
- History of sudden or rapidly progressive hearing loss within the previous 90 days.
- Acute or chronic dizziness.
- Unilateral hearing loss of sudden or recent onset within the previous 90 days.
- Audiometric air-bone gap equal to or greater than 15 decibels at 500 Hz, 1000 Hz, and 2000 Hz.
- Visible evidence of significant cerumen accumulation or a foreign body in the ear canal.
- Pain or discomfort in the ear.

A record of the signed medical evaluation or waiver statement

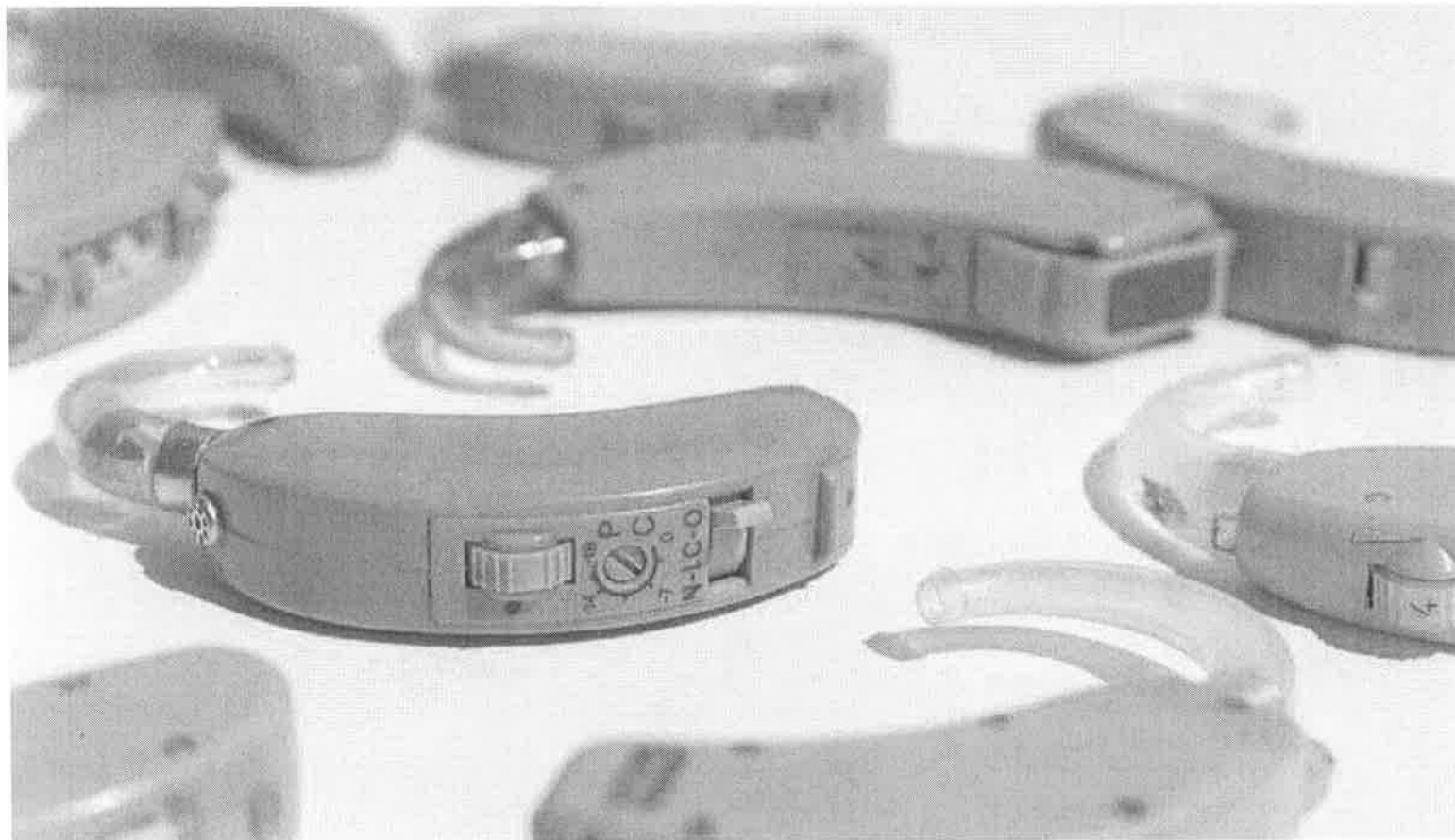
must be retained by the dispenser for a period of three years after the dispensing of the hearing aid. Exemptions from the medical evaluation and waiver include qualified schools or institutions purchasing auditory trainers (e.g., soundfield FM systems) for communicating with and educating those with hearing loss.

Prior to signing the earlier mentioned statement, the patient must be provided an opportunity to review the user instructional brochure for a hearing aid that has been or may be selected for the prospective user. This brochure should be reviewed orally, and time should be allowed for the patient to read this as well. If the brochure is not available, the patient should be provided the name

and address of the manufacturer or distributor of the brochure in order to obtain a copy.

The user instructional brochure provided by the manufacturer shall include the following components to the extent they are applicable to the particular requirements and characteristics of the hearing aid:

- Hearing aid illustration, controls, user adjustments, and battery compartment.
- Information on control functions.
- Accessory descriptions (e.g., for use with the television or phone).
- Hearing aid use instructions.
- Maintenance and care of the aid.
- Replacing or recharging batteries.
- How to obtain repair service (including at least one specific address to obtain service).
- Description of conditions to avoid (e.g., dropping aid or exposing to excessive heat).
- Side effect identification that may warrant consultation with physician (e.g., skin irritation).
- Statement that the aid will not restore normal hearing and will not prevent or improve a hearing



impairment resulting from organic conditions.

- Statement that infrequent usage does not permit them to attain full benefit.
- Statement that use of a hearing aid is only part of hearing habilitation and may need to be supplemented by auditory training and instruction in lipreading.

The user instructional brochure should contain the following notice:

### **Important Notice for Prospective Hearing Aid Users**

Good health practice requires that a person with a hearing loss have a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing aid. Licensed physicians who specialize in diseases of the ear are often referred to as otolaryngologists, otologists, or otorhinolaryngologists. The purpose of medical evaluation is to assure that all medically treatable conditions that may affect hearing are identified and treated before the hearing aid is purchased.

Following the medical evaluation, the physician

will give you a written statement that states that your hearing loss has been medically evaluated and that you may be considered a candidate for a hearing aid. The physician will refer you to an audiologist or a hearing aid dispenser, as appropriate, for a hearing aid evaluation.

The audiologist or hearing aid dispenser will conduct a hearing aid evaluation to assess your ability to hear with and without a hearing aid. The hearing aid evaluation will enable the audiologist or dispenser to select and fit a hearing aid to your individual needs.

If you have reservations about your ability to adapt to amplification, you should inquire about the availability of a trial-rental or purchase-option program. Many hearing aid dispensers now offer programs that permit you to wear a hearing aid for a period of time for a nominal fee after which you may decide if you want to purchase the hearing aid.

Federal law restricts the sale of hearing aids to those individuals who have obtained a medical evaluation from a licensed

physician. Federal law permits a fully informed adult to sign a waiver statement declining the medical evaluation for religious or personal beliefs that preclude consultation with a physician. The exercise of such a waiver is not in your best health interest and its use is strongly discouraged.

**Children with Hearing Loss:** In addition to seeing a physician for a medical evaluation, a child with hearing loss should be directed to an audiologist for evaluation and rehabilitation since hearing loss may cause problems in language development and the educational and social growth of a child. An audiologist is qualified by training and experience to assist in the evaluation and rehabilitation of a child with a hearing loss.

A warning statement to hearing aid dispensers must also be in the brochure listing the red flags requiring the conditions that should prompt a physician referral as listed earlier (e.g., acute or chronic dizziness, audiometric air-bone gaps, etc.).

Technical data pertaining to the performance of the hearing aid can either be provided in the user brochure or in separate labeling that accompanies the device, including SSPL 90 curve, frequency response curve, HF-Average SSPL 90, HF-Average full-on gain, reference test gain, frequency range, total harmonic distortion, equivalent input noise, battery drain, induction

### **ALSO OF INTEREST**

*Joint Statement on Consumer-Administered Hearing Tests and Direct-to-Consumer Hearing Aid Sales*

Visit [www.audiology.org](http://www.audiology.org) and search keywords "direct-to-consumer" or use the QR code to view the document on your mobile device.



coil sensitivity, and attack and release times.

Hearing aids must be clearly and permanently labeled with the name of the manufacturer, model name or number, serial number, and year of manufacture. Additionally a "+" symbol must be used as a label to indicate correct battery insertion unless it is physically impossible to insert the battery in the reversed position. If the patient is purchasing a used or rebuilt hearing aid, this must be stated on the aid's packaging as well as on a tag that is physically attached to the hearing aid.

It should also be noted that trial periods are not regulated by the federal government but are typically specified by the individual state. Many states require a 30-day trial period, but you will need to check with your own state's applicable licensure law(s) or related state regulations. Additionally, the state may provide guidelines on what to include in the hearing aid contract (i.e., if the hearing aid is used or reconditioned, provider's license number, make and model of hearing aid).

For a complete listing of the above regulations, visit [www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm), then type "801.420" or "801.421" in the Title21 Part. Section box.

## Discussion of FTC Guidance

The FTC, also known as the Bureau of Consumer Protection, works to combat deceptive business practice and consumer fraud. The agency provides information for the consumer directed at guiding them through the process of obtaining a hearing aid. A description of the types of hearing loss and the differences between hearing health-care professionals are outlined. The FTC breaks down the

components of a purchase agreement and key elements that the potential user should be attuned to, including the trial and warranty period, purchase cost, and options of future loaner devices.


The FTC provides a description of the parts of a hearing aid, as well as comparisons between a hearing aid and a personal sound amplification product. Recommendations are set forth for seeking the use of a hearing aid over the latter to expedite diagnosis and any potential treatable conditions. Additionally, direction is offered on how to locate a hearing health-care professional, offering several types of hearing aid manufacturers to select from. For more information, review the FTC document titled *Sound Advice on Hearing Aids*, which can be found at [www.ftc.gov/bcp/edu/pubs/consumer/health/hea10.shtm](http://www.ftc.gov/bcp/edu/pubs/consumer/health/hea10.shtm).

To report deceptive business practices or other types of consumer fraud, contact the FTC at [www.ftc.gov/complaint](http://www.ftc.gov/complaint) or call 1-877-382-4357 (TTY: 1-866-653-4261).

## Current Issues

The recent advent of hearing aid sales made over the Internet has raised many questions about the compliance and enforcement of FDA regulations in this forum. The most notable issue pertains to the insurance companies United Healthcare and hi HealthInnovations (UHC/Hi) who have begun offering online hearing tests and the online purchase of hearing aids. Without the involvement of a hearing health-care professional, concerns regarding patient health and safety are at the forefront.

The FDA has been made aware of these issues through the advocacy of the Academy, as well as other professional organizations and hearing health-care professionals, and has

issued a statement citing that the sale of hearing aids over the Internet must comply with the "spirit" of the medical evaluation. The FDA has requested that Academy members forward information to them when members learn of Internet sites that allow consumers to make hearing aid purchases by simply checking a box to waive the medical evaluation. The FDA states that it will investigate each reported Internet site to determine if the waiver follows the requirements of *Code of Federal Regulations* Title 21 as discussed previously. To report concerns regarding the sale of hearing aids over the Internet, you can send an e-mail to [webcomplaints@ora.fda.gov](mailto:webcomplaints@ora.fda.gov). Additional FDA guidance, "Buying Medical Devices and Diagnostic Tests Online," can be found on the FDA Web site at [www.fda.gov/MedicalDevices/ResourcesforYou/Consumers/BuyingMedicalDevicesandDiagnosticTestsOnline/default.htm](http://www.fda.gov/MedicalDevices/ResourcesforYou/Consumers/BuyingMedicalDevicesandDiagnosticTestsOnline/default.htm). 

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*NOTE: At the time of publication, the Academy learned that the FDA issued a cease and desist letter with regard to the online hearing test offered by UHC/Hi. In the letter, the FDA asserts that UHC/Hi is in violation of the Federal Food, Drug, and Cosmetic Act, which requires marketing clearance or approval of devices by the FDA. Please see the Academy's Web site for the most up-to-date news on this topic.*

TITLE 21--FOOD AND DRUGS  
CHAPTER I--FOOD AND DRUG ADMINISTRATION  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
SUBCHAPTER H--MEDICAL DEVICES

PART 801 -- LABELING

Subpart H--Special Requirements for Specific Devices

Sec. 801.421 Hearing aid devices; conditions for sale.

(a) *Medical evaluation requirements* -- (1) *General*. Except as provided in paragraph (a)(2) of this section, a hearing aid dispenser shall not sell a hearing aid unless the prospective user has presented to the hearing aid dispenser a written statement signed by a licensed physician that states that the patient's hearing loss has been medically evaluated and the patient may be considered a candidate for a hearing aid. The medical evaluation must have taken place within the preceding 6 months.

(2) *Waiver to the medical evaluation requirements*. If the prospective hearing aid user is 18 years of age or older, the hearing aid dispenser may afford the prospective user an opportunity to waive the medical evaluation requirement of paragraph (a)(1) of this section provided that the hearing aid dispenser:

(i) Informs the prospective user that the exercise of the waiver is not in the user's best health interest;

(ii) Does not in any way actively encourage the prospective user to waive such a medical evaluation; and

(iii) Affords the prospective user the opportunity to sign the following statement:

I have been advised by \_\_\_\_\_ (Hearing aid dispenser's name) that the Food and Drug Administration has determined that my best health interest would be served if I had a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing aid. I do not wish a medical evaluation before purchasing a hearing aid.

(b) *Opportunity to review User Instructional Brochure*. Before signing any statement under paragraph (a)(2)(iii) of this section and before the sale of a hearing aid to a prospective user, the hearing aid

dispenser shall:

(1) Provide the prospective user a copy of the User Instructional Brochure for a hearing aid that has been, or may be selected for the prospective user;

(2) Review the content of the User Instructional Brochure with the prospective user orally, or in the predominate method of communication used during the sale;

(3) Afford the prospective user an opportunity to read the User Instructional Brochure.

*(c) Availability of User Instructional Brochure.* (1) Upon request by an individual who is considering purchase of a hearing aid, a dispenser shall, with respect to any hearing aid that he dispenses, provide a copy of the User Instructional Brochure for the hearing aid or the name and address of the manufacturer or distributor from whom a User Instructional Brochure for the hearing aid may be obtained.

(2) In addition to assuring that a User Instructional Brochure accompanies each hearing aid, a manufacturer or distributor shall with respect to any hearing aid that he manufactures or distributes:

(i) Provide sufficient copies of the User Instructional Brochure to sellers for distribution to users and prospective users;

(ii) Provide a copy of the User Instructional Brochure to any hearing aid professional, user, or prospective user who requests a copy in writing.

*(d) Recordkeeping.* The dispenser shall retain for 3 years after the dispensing of a hearing aid a copy of any written statement from a physician required under paragraph (a)(1) of this section or any written statement waiving medical evaluation required under paragraph (a)(2)(iii) of this section.

*(e) Exemption for group auditory trainers.* Group auditory trainers, defined as a group amplification system purchased by a qualified school or institution for the purpose of communicating with and educating individuals with hearing impairments, are exempt from the requirements of this section.



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Sec. 801.420 Hearing aid devices; professional and patient labeling.

*(a) Definitions for the purposes of this section and 801.421.*

*(1) Hearing aid* means any wearable instrument or device designed for, offered for the purpose of, or represented as aiding persons with or compensating for, impaired hearing.

*(2) Ear specialist* means any licensed physician who specializes in diseases of the ear and is medically trained to identify the symptoms of deafness in the context of the total health of the patient, and is qualified by special training to diagnose and treat hearing loss. Such physicians are also known as otolaryngologists, otologists, and otorhinolaryngologists.

*(3) Dispenser* means any person, partnership, corporation, or association engaged in the sale, lease, or rental of hearing aids to any member of the consuming public or any employee, agent, sales person, and/or representative of such a person, partnership, corporation, or association.

*(4) Audiologist* means any person qualified by training and experience to specialize in the evaluation and rehabilitation of individuals whose communication disorders center in whole or in part in the hearing function. In some states audiologists must satisfy specific requirements for licensure.

*(5) Sale or purchase* includes any lease or rental of a hearing aid to a member of the consuming public who is a user or prospective user of a hearing aid.

*(6) Used hearing aid* means any hearing aid that has been worn for any period of time by a user. However, a hearing aid shall not be considered "used" merely because it has been worn by a prospective user as a part of a bona fide hearing aid evaluation conducted to determine whether to select that particular hearing aid for that

prospective user, if such evaluation has been conducted in the presence of the dispenser or a hearing aid health professional selected by the dispenser to assist the buyer in making such a determination.

(b) *Label requirements for hearing aids.* Hearing aids shall be clearly and permanently marked with:

(1) The name of the manufacturer or distributor, the model name or number, the serial number, and the year of manufacture.

(2) A "+" symbol to indicate the positive connection for battery insertion, unless it is physically impossible to insert the battery in the reversed position.

(c) *Labeling requirements for hearing aids -- (1) General.* All labeling information required by this paragraph shall be included in a User Instructional Brochure that shall be developed by the manufacturer or distributor, shall accompany the hearing aid, and shall be provided to the prospective user by the dispenser of the hearing aid in accordance with 801.421(c). The User Instructional Brochure accompanying each hearing aid shall contain the following information and instructions for use, to the extent applicable to the particular requirements and characteristics of the hearing aid:

(i) An illustration(s) of the hearing aid, indicating operating controls, user adjustments, and battery compartment.

(ii) Information on the function of all controls intended for user adjustment.

(iii) A description of any accessory that may accompany the hearing aid, e.g., accessories for use with a television or telephone.

(iv) Specific instructions for:

(a ) Use of the hearing aid.

(b ) Maintenance and care of the hearing aid, including the procedure to follow in washing the earmold, when replacing tubing on those hearing aids that use tubing, and in storing the hearing aid when it will not be used for an extended period of time.

(c ) Replacing or recharging the batteries, including a generic designation of replacement batteries.

(v) Information on how and where to obtain repair service, including at least one specific address where the user can go, or send the hearing aid to, to obtain such repair service.

(vi) A description of commonly occurring avoidable conditions that could adversely affect or damage the hearing aid, such as dropping,

immersing, or exposing the hearing aid to excessive heat.

(vii) Identification of any known side effects associated with the use of a hearing aid that may warrant consultation with a physician, e.g., skin irritation and accelerated accumulation of cerumen (ear wax).

(viii) A statement that a hearing aid will not restore normal hearing and will not prevent or improve a hearing impairment resulting from organic conditions.

(ix) A statement that in most cases infrequent use of a hearing aid does not permit a user to attain full benefit from it.

(x) A statement that the use of a hearing aid is only part of hearing habilitation and may need to be supplemented by auditory training and instruction in lipreading.

(xi) The warning statement required by paragraph (c) (2) of this section.

(xii) The notice for prospective hearing aid users required by paragraph (c) (3) of this section.

(xiii) The technical data required by paragraph (c) (4) of this section, unless such data is provided in separate labeling accompanying the device.

(2) *Warning statement.* The User Instructional Brochure shall contain the following warning statement:

## **Warning to Hearing Aid Dispensers**

A hearing aid dispenser should advise a prospective hearing aid user to consult promptly with a licensed physician (preferably an ear specialist) before dispensing a hearing aid if the hearing aid dispenser determines through inquiry, actual observation, or review of any other available information concerning the prospective user, that the prospective user has any of the following conditions:

(i) Visible congenital or traumatic deformity of the ear.

(ii) History of active drainage from the ear within the previous 90 days.

(iii) History of sudden or rapidly progressive hearing loss within

the previous 90 days.

(iv) Acute or chronic dizziness.

(v) Unilateral hearing loss of sudden or recent onset within the previous 90 days.

(vi) Audiometric air-bone gap equal to or greater than 15 decibels at 500 hertz (Hz), 1,000 Hz, and 2,000 Hz.

(vii) Visible evidence of significant cerumen accumulation or a foreign body in the ear canal.

(viii) Pain or discomfort in the ear.

Special care should be exercised in selecting and fitting a hearing aid whose maximum sound pressure level exceeds 132 decibels because there may be risk of impairing the remaining hearing of the hearing aid user. (This provision is required only for those hearing aids with a maximum sound pressure capability greater than 132 decibels (dB).)

(3) *Notice for prospective hearing aid users.* The User Instructional Brochure shall contain the following notice:

## **Important Notice for Prospective Hearing Aid Users**

Good health practice requires that a person with a hearing loss have a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing aid. Licensed physicians who specialize in diseases of the ear are often referred to as otolaryngologists, otologists or otorhinolaryngologists. The purpose of medical evaluation is to assure that all medically treatable conditions that may affect hearing are identified and treated before the hearing aid is purchased.

Following the medical evaluation, the physician will give you a written statement that states that your hearing loss has been medically evaluated and that you may be considered a candidate for a hearing aid. The physician will refer you to an audiologist or a hearing aid dispenser, as appropriate, for a hearing aid evaluation.

The audiologist or hearing aid dispenser will conduct a hearing aid evaluation to assess your ability to hear with and without a hearing aid. The hearing aid evaluation will enable the audiologist or

dispenser to select and fit a hearing aid to your individual needs.

If you have reservations about your ability to adapt to amplification, you should inquire about the availability of a trial-rental or purchase-option program. Many hearing aid dispensers now offer programs that permit you to wear a hearing aid for a period of time for a nominal fee after which you may decide if you want to purchase the hearing aid.

Federal law restricts the sale of hearing aids to those individuals who have obtained a medical evaluation from a licensed physician. Federal law permits a fully informed adult to sign a waiver statement declining the medical evaluation for religious or personal beliefs that preclude consultation with a physician. The exercise of such a waiver is not in your best health interest and its use is strongly discouraged.

## children with hearing loss

In addition to seeing a physician for a medical evaluation, a child with a hearing loss should be directed to an audiologist for evaluation and rehabilitation since hearing loss may cause problems in language development and the educational and social growth of a child. An audiologist is qualified by training and experience to assist in the evaluation and rehabilitation of a child with a hearing loss.

(4) *Technical data.* Technical data useful in selecting, fitting, and checking the performance of a hearing aid shall be provided in the User Instructional Brochure or in separate labeling that accompanies the device. The determination of technical data values for the hearing aid labeling shall be conducted in accordance with the test procedures of the American National Standard "Specification of Hearing Aid Characteristics," ANSI S3.22-2003 (Revision of ANSI S3.22-1996) (Includes April 2007 Erratum). The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Standards Secretariat of the Acoustical Society of America, 120 Wall St., New York, NY 10005-3993, or are available for inspection at the Regulations Staff, CDRH (HFZ-215), FDA, 1350 Piccard Dr., rm. 150, Rockville, MD 20850, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html). As a minimum, the User Instructional Brochure or such other labeling shall include the appropriate values or information for the following technical data elements as these elements are defined or used in such standard:

- (i) Saturation output curve (SSPL 90 curve).

- (ii) Frequency response curve.
- (iii) Average saturation output (HF-Average SSPL 90).
- (iv) Average full-on gain (HF-Average full-on gain).
- (v) Reference test gain.
- (vi) Frequency range.
- (vii) Total harmonic distortion.
- (viii) Equivalent input noise.
- (ix) Battery current drain.
- (x) Induction coil sensitivity (telephone coil aids only).
- (xi) Input-output curve (ACG aids only).
- (xii) Attack and release times (ACG aids only).

(5) *Statement if hearing aid is used or rebuilt.* If a hearing aid has been used or rebuilt, this fact shall be declared on the container in which the hearing aid is packaged and on a tag that is physically attached to such hearing aid. Such fact may also be stated in the User Instructional Brochure.

(6) *Statements in User Instructional Brochure other than those required.* A User Instructional Brochure may contain statements or illustrations in addition to those required by paragraph (c) of this section if the additional statements:

- (i) Are not false or misleading in any particular, e.g., diminishing the impact of the required statements; and
- (ii) Are not prohibited by this chapter or by regulations of the Federal Trade Commission.

[42 FR 9294, Feb. 15, 1977, as amended at 47 FR 9398, Mar. 5, 1982; 50 FR 30154, July 24, 1985; 54 FR 52396, Dec. 21, 1989; 64 FR 59620, Nov. 3, 1999; 69 FR 18803, Apr. 9, 2004; 73 FR 31360, June 2, 2008]